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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/801,918	03/16/2004	Hernan Altman	132733	132733 3090	
7590 06/28/2006			EXAM	EXAMINER	
Dean D. Small Armstrong Teasdale LLP Suite 2600 One Metropolitan Square			SUCHECKI, KRYSTYNA		
			ART UNIT	PAPER NUMBER	
			2882		
St. Louis, MO	63102		DATE MAILED: 06/28/2006	DATE MAILED: 06/28/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/801,918	ALTMAN, HERNAN				
Office Action Summary	Examiner	Art Unit				
	Krystyna Suchecki	2882				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period was reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 20 Ma						
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,—	) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-17 and 19-29</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,3-17,19-29</u> is/are rejected.						
<ul> <li>7)  Claim(s) 2 is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or</li> </ul>	colection requirement					
o) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	r.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
11) The oath of declaration is objected to by the Ex	aminer. Note the attached Office	ACTION OF IOTH PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of	or the certified copies not receive	ea.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Notice of Informal Patent Application (PTO-152)						
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)  6) Other:						

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-5 and 7-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Amemiya (US 2004/0081277).

Regarding claims 1, 3 and 4, Figure 6 of Amemiya teaches a method of examining a patient, the method comprising: aligning a patient table in an opening of a gantry that includes a CZT photon detector (Paragraph 53; detection section 65) and an x-ray source (42); imaging a patient utilizing a first imaging modality (t1) during a first portion of a scan using the CZT detector; imaging the patient utilizing a second imaging modality (t2) during a second portion of the scan using the CZT detector wherein the second imaging modality is different than the first imaging modality; and imaging the patient utilizing the first imaging modality (t3) during a third portion of the scan using the CZT detector (Paragraphs 64, 68, 75-79). Amemiya teaches a method further comprising moving the patient table (16) along at least one of a patient table orthogonal axis when imaging the patient utilizing at least one of the first imaging modality and the second imaging modality (movement via controller 47); a method further comprising

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rotating the gantry around a longitudinal axis of the patient table when imaging the patient utilizing at least one of the first imaging modality and the second imaging modality (Paragraphs 107, 141, 147).

Regarding Claim 5, Figures 12 and 13 of Amemiya teach a method wherein the x-ray source is configured to emit x-rays in a beam having a predetermined fan angle, said method further comprising rotating the gantry around a longitudinal axis of the patient table less than one hundred and eighty degrees of rotation when imaging the patient utilizing at least one of the first imaging modality and the second imaging modality. Amemiya teaches this since the slit for x-ray source traversal upon a gantry can be seen in the figures to be less that a full rotation, and possibly 180 Degrees plus the fan width. Amemiya starts rotation and stops rotation at several places along the circumference of the slit, thereby causing a rotation of less than 180 Degrees (Embodiment 3, Paragraphs 115-133).

Regarding Claim 7, Amemiya teaches a method further comprising moving the patient table to follow a contour of the patient during at least a portion of a scan (the table is moved to obtain images of an affected area; Paragraphs 118, 127 and 108-109).

Regarding Claim 8, Figure 6, and throughout the disclosure, Amemiya teaches a method wherein the patient includes a radiopharmecuetical (Paragraphs 124 and 118) and wherein imaging the patient utilizing a first imaging modality comprises imaging the patient using a nuclear medicine modality. Amemiya reverses which modality is first or

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second between the embodiments, showing a lack of criticality of which modality begins or ends the imaging process.

Regarding Claims 9 and 10, Memiya teaches a method wherein imaging the patient using a nuclear medicine modality comprises imaging the patient using single positron emission computed tomography (SPECT) (Paragraph 1) and a method wherein imaging the patient using a nuclear medicine modality comprises imaging the patient using a pair of photon detectors using a SPECT modality (Paragraph 132).

Regarding Claim 11, Figure 6 of Amemiya teaches a method wherein imaging a patient utilizing a first imaging modality comprises imaging the patient using a computer tomography (CT) modality.

Regarding claim 12, Amemiya teaches a method wherein imaging the patient using a CT modality comprises imaging the patient using a cone-beam CT modality (Paragraph 107).

Claims 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Karellas (US 2003/0169847).

Regarding Claims 14 and 15 An imaging system comprising a gantry unit having an x-ray source (112) for generating x-rays and a CZT detector (Paragraphs 8 and 121) configured to detect emission gamma photons and transmission x-ray photons, and a C-arm (Figure 3B) configured to move the x-ray source and detector along an image acquisition path between at least first and second imaging positions. The gantry is at least one of rotatably coupled to a gantry holder and slidably coupled to the gantry

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holder (Figure 3B). The x-ray source comprises a cone-beam x-ray source (Figure 3A and 53).

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amemiya in view of Besson.

Regarding Claim 6, Amemiya teaches that x-ray imaging, a first imaging modality, can be performed with the rotation extent and speed of rotation of a fan beam x-ray source controlled based upon the image desired (Embodiment 3; paragraphs 115-131).

Amemiya fails to disclose a method further comprising rotating the gantry around a longitudinal axis of the patient table approximately one hundred and eighty degrees plus the fan angle of rotation when imaging the patient utilizing at least one of the first imaging modality and the second imaging modality.

Besson teaches a method wherein the x-ray source is configured to emit x-rays in a beam having a predetermined fan angle, said method further comprising rotating the gantry around a longitudinal axis of the patient table approximately one hundred and eighty degrees plus the fan angle of rotation when imaging the patient utilizing at least one of the first imaging modality and the second imaging modality (Column 4, line 46-

Column 6, line 2). The degree of rotation prevents dose waste or distortion of a slice sensitivity profile (Column 6, lines 1-2) and allows for the use of a minimum amount of data to produce an accurate three-dimensional image (Column 7, line 23-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Besson, including rotation of a gantry around a patient table approximately one hundred and eighty degrees plus the fan angle of rotation when imaging the patient utilizing x-ray imaging in order to prevent dose waste or distortion of a slice sensitivity profile, and to allow for the use of a minimum amount of data to produce an accurate three-dimensional image.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amemiya in view of Mao (US 6,708,052).

Regarding Claim 13, Amemiya turns an x-ray signal on and off between motions of the x-ray source during multi-modality imaging as above. An operator can select scan times and speeds so that the on/off times of the x-ray source can be chosen (Embodiment 3).

Amemiya fails to expressly teach monitoring a cyclic physiological function within the patient; and triggering at least one of the first modality and the second modality during at least one preselected portion of the cyclical physiological function.

Mao teaches x-ray imaging including monitoring a cyclic physiological function within the patient; and triggering the x-ray imaging during at least one preselected portion of the cyclical physiological function. The system of Mao is disclosed as usable

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with many different kinds of modalities (Column 4), and minimizes motion artifacts (Title). Mao allows an operator to input imaging parameters (Column 4), but the monitoring device primarily functions to determine the ideal point in the physiological function to perform imaging.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a monitoring device as taught by Mao in the system of Amemiya in order to perform the intermittent imaging of Amemiya at an ideal point in a physiological function so as to minimize motion artifacts. The ability of the operator to maintain control over the x-ray data acquisition in both devices would allow the monitoring device to compliment the speed and extent features of Amemiya.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karellas in view of Besson.

Regarding Claim 16, Karellas desires that the C-arm device of the invention perform three-dimensional angiography for cardiac diagnosis, but fails to discuss the C-arm rotation moved to form the image. The x-ray source is configured to emit x-rays in a beam having a predetermined fan angle (Figures 3A and 8).

Besson teaches a method wherein the x-ray source is configured to emit x-rays in a beam having a predetermined fan angle, said method further comprising rotating the gantry around a longitudinal axis of the patient table approximately one hundred and eighty degrees plus the fan angle of rotation when imaging the patient utilizing at least one of the first imaging modality and the second imaging modality (Column 4, line 46-

Column 6, line 2). The degree of rotation prevents dose waste or distortion of a slice sensitivity profile (Column 6, lines 1-2) and allows for the use of a minimum amount of data to produce an accurate three-dimensional image (Column 7, line 23-32). The scan method is especially useful for x-ray image acquisition in light of patient heart rates (Columns 1 and 5).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Besson, including rotation of a gantry around a patient table approximately one hundred and eighty degrees plus the fan angle of rotation when imaging the patient utilizing x-ray imaging in order to prevent dose waste or distortion of a slice sensitivity profile, and to allow for the use of a minimum amount of data to produce an accurate three-dimensional image. Using the method of Besson would compliment Karellas' desire to perform three-dimensional cardiac imaging by complimenting at least the x-ray image acquisistion of Karellas.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karellas in view of Senzig (US 7,016,457).

Regarding Claims 19-23, Karellas teaches a multi-mode imaging apparatus where a C-arm gantry collects imaging data as above for claim 14, and includes fluoroscopic data collection utilizing a CZT detector, where the detector are positioned substantially perpendicularly opposed to an x-ray source.

Karellas fails to teach an imaging system wherein said detector comprises a pair of detectors inclined at an angle of approximately ninety degrees with respect to each other.

Senzig teaches a multi-mode imaging apparatus (Column 6) where a C-arm gantry collects imaging data and wherein said detector comprises a pair of detectors (102, 104) inclined at an angle of approximately ninety degrees with respect to each other (Figure 6). The angled detectors allow triangulation methods to be employed to find discrete structures within a patient (Column 7, line 64- Column 8, line 9). The detectors may be angled or made flat based upon the imaging mode selected, but are angled advantageously for fluoroscopic mode imaging. The detector of Senzig can include direct detection devices (Column 4, lines 35-37) and is perpendicularly opposed to an x-ray source.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the angled detectors of Senzig in the device of Karellas for the benefit of using triangulation methods to find discrete structures within a patient. The angled detection of Senzig would compliment the detection in Karellas since both Karellas and Senzig desire fluoroscopic imaging. Senzig implies the use of a CZT detector by referencing the direct detection type of detector, and so the system of Senzig would not conflict with the direct detection system of Karellas.

Claims 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karellas in view of Ivan (US 6,364,526).

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Regarding Claims 24-29, Karellas teaches a fluoroscopic imaging system comprising a gantry unit as above for claim 14, but does not teach the criticality of motions performed by a c-arm gantry or patient table.

Ivan teaches a fluoroscopic imaging system comprising a patient table configured to translate along at least one of three axes (Column 5, lines 1-13); wherein said system is configured to control at least one of the patient table and the gantry to cause the detector to follow a contour of an object to be scanned (Column 6, lines 1-7); including an imaging isocentric area located between said x-ray source and said detector, said imaging isocentric area remaining substantially constant when said gantry moves along said image acquisition path (Column 6); wherein said imaging system comprises a gantry support base wherein said support base is coupled to a rail system, said rail system operable to move said gantry unit along at least one axes (Figures 7 and 9); wherein said rail system is coupled to at least one of a floor, a ceiling, and a wall of an examination room (Figures 7 and 9); wherein said imaging system comprises a gantry support base wherein said gantry support base is a mobile support base (Column 2, lines 51-60). Ivan teaches these flexible design solutions for c-arm movement and patient movement upon a table so as to limit radiation exposure to an interventional person, reduce scheduling conflicts, and reduce patient motion from transfer of the patient between multiple devices (Column 1- Column 2, line 5).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the c-arm and table motion alternatives of Ivan in the system of Karellas in order to give the system of Karellas limited radiation exposure

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to an interventional person, reduced scheduling conflicts, and reduced patient motion from transfer of the patient between multiple devices (Ivan, Column 1- Column 2, line 5). Though Ivan does not expressly teach gamma radiation detection in the manner of Karellas, Karellas would still benefit from isocenter and other mobility improvements since the improvements of Ivan would not detract from the imaging capabilities of Karellas, but would improve the safety and usability of Karellas' device.

#### Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 2 contains allowable subject matter for at least the reason that the prior art of record fails to teach or reasonably suggest a method of examining a patient comprising aligning a patient table in an opening of a gantry of a C-arm unit that includes a CZT photon detector and an x-ray source, imaging a patient using a first imaging modality using the CZT detector; imaging the patient using a second imaging modality using the CZT detector; and imaging the patient again utilizing the first imaging modality and the CZT detector as claimed. Though Amemiya teaches a method of alternating between first and second imaging modalities and teaches the use of a CZT photon detector for both modalities, there is no suggestion in Amemiya to utilize a C-arm unit. The photon detection of Amemiya requires a ring of detectors for adequate signal collection, and there is no suggestion to modify the detection area to fit a C-arm in view of the timing sequence requirements.

## Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments, see Response, filed 03/20/06, with respect to the rejection(s) of claim(s) 14-17 and 19-9 under Kojima have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Karellas and others as set forth above.

Applicant's arguments include a citation to <u>In re Vaeck</u>, which should be to 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991) [emphasis added].

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krystyna Suchecki whose telephone number is (571) 272-2495. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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EDWARD J. GLICK